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#### Purpose and scope of the research effort.

Goals: This is one project in a planned program of research to improve care for injured Operation Enduring Freedom/Operation Iraqi freedom (OEF/OIF) veterans. Building on the successful, currently funded, CDMRP study "Effectiveness of Telerehabilitation for OIF/OEF returnees with Combat Related Trauma": W81XWH08-2-0091 we propose with this research to extend our analysis to evaluating the effectiveness of the telerehabilitation intervention for veterans with combat related trauma. We plan to test its effectiveness with a cohort of OIF/OEF returnees discharged from the James A Haley Veterans Hospital in Tampa, Fl (Tampa VA) and the Bruce B Carter VA Medical Center at Miami (Miami VA).

The *long term* goal of this program of research is to optimally define telerehabilitation services for all veterans with polytrauma, including accurate and efficient screening instruments, educational material for patients and families, family support, and family counseling to enhance care coordination and to maximize functional outcomes and quality of life.

#### Overall progress to date and problem areas

#### **Statement of Work**

#### Obtain Institutional Review Board and conduct literature review.

1) Modified IRB and Informed Consents for the study have been approved by the University of South Florida and the Miami VA to facilitate enrollment of subjects. All required documents for project approval have been forwarded to USAMRMC. Clearance has been obtained from HRPO (DoD) to commence our study.

#### **Care Coordination Team**

Our telerehabilitation care coordination team is organized under Steve Scott, MD, Chief Physical Medicine and Rehabilitation Services VA at the Tampa VA and Stuti Dang, MD at the Miami VA. Vilma Rosada, RN is in charge of care coordination and recruitment of combat wounded OEF/OIF veterans via telerehabilitation at Tampa. Assisting her are Andy Lapcevic an expert in information technology and data management together with Steve Moore MS, website coordinator. Andrea Spehar, JD, DM, MPH will be the project manager at the Tampa VA. Ms. Blanco Barreto, RN is the care coordinator efforts at The Miami VA.

#### **Data collection and Care Coordination.**

Instruments for data collection are posted on **Surveymonkey** a commercial website that was cleared by VA Information Security at the James Haley Veterans Hospital as meeting the requirements for a secure website. Details on Surveymonkey can be found at surveymonkey.com. Participants in the study will access the website to answer surveys which will be downloaded and maintained in an Access database for analysis purposes. We have created a blog site on the VA server at Gainesville, Fl that serves as the main conduit for communication between care

coordinators and study enrollees. Separate "virtual rooms" for Tampa and Miami have been constructed at the VA server to facilitate care coordination at the two sites without compromising patient confidentiality. At least once a week communication is initiated between care coordinators and study participants.

*Monitoring health outcomes*: Veterans are required to connect (via the internet) to a secured commercial website (SurveyMonkey<sup>R</sup>) to provide, periodically, repeated measures of response to a variety of instruments to monitor their health outcomes over time including the Functional Independence and Functional Assessment Measure<sup>TM</sup>, the Craig Handicap Assessment and Reporting Technique, the Patient Competency Rating, the PTSD Checklist Military Form, Modified PTSD Symptom Scale, Self-Report Alcohol Use Disorders Identification Test, Self Report Beck Depression Inventory and the Medical Outcomes Social Support Survey.

#### **Patient Recruitment**

A total of approximately 120 veterans equally distributed among the intervention and control groups have been recruited at the Tampa and Miami facilities. We expect to eventually collect the required data from a smaller cohort of patients due to veterans moving away from the area or being dis-enrolled due to non-participation in the study.

#### **Body**

#### **Statement of Work**

#### Effectiveness of Telerehabilitation for OIF/OEF returnees with Combat related Trauma.

*Task 1.* Administrative tasks, Months 1-3

Completed

- a. Obtain Institutional Review Board and conduct literature review.
- b. Recruit care coordinator (ARNP) and program manager at the Miami VA facility.
- c. Order computers, load software programs/survey instruments and set up web site on VA servers.
- d. Recruit veterans for the control group at the Tampa VA.

*Task 2.* Patient recruitment and programming, Months 3-32:

Completed

- 1. Finalize list of all OEF/OIF returnees discharged from the Miami VA with a primary or secondary diagnosis of TBI.
- 2. Contact (phone/internet/mail) patients who meet inclusion criterion and agree to participate in telerehab and have informed consents signed at the Tampa and Miami VAs.
- 3. Provide access privileges to enrollees to telerehab website.

*Task 3.* Data Collection: Months 5-32.

**Ongoing** 

- 1. Abstract from the Veterans' health Information Systems & Technology Architecture (VistA) medical record abstracts pertaining to health care utilization and treatments of combat wounded veterans.
- 2. Abstract from the VA Decision Support System (DSS) cost estimates of VA Health Care Utilization.
- 3. Obtain responses to instruments to capture function. cognition, ability, integration into society
- 4. Conduct patient/caregiver satisfaction surveys and perceptions on facilitators and barriers to telerehabilitation.

Task 4. Data Analysis: Months 32-36.

To be started

- a. Conduct multivariate statistical analysis and economic modeling to:
  - a) Determine changes in functional/cognition and community integration
  - b) Characterize changes in status of Post Traumatic Stress Disorders.

- c) Identify changes in patterns of healthcare utilization and associated costs
- d) Evaluate the cost effectiveness of telerehabilitation.
- b. Conduct interviews to synthesize facilitators and barriers to providing telerehabilitation for TBI.

Task 5. Report Writing: Months 36-40

To be started

a. Prepare final report and initial manuscripts.

#### **Patient Recruitment**

Table 1 indicates subject characteristics of all 120 veterans enrolled in the study at the Tampa and Miami facilities. This report summarizes our findings for the veterans who completed baseline surveys. Four veterans were female. Females cannot be enlisted in combat units but do sustain injuries due to accidents and indirect fire. The majority of veterans enrolled classified themselves as white and were between 18 and 29 years of age.

**Table 1: Subject Characteristics (N=120)** 

	Tampa	Miami
Gender	N (%)	N (%)
Female	4 (6.7)	5 (8.3)
Male	56 (93.3)	55 (91.7)
Race		
Black	12 (20.0)	8 (13.3)
Native American	1 (1.7)	0
Native Hawaiian	1 (1.7)	0
White	46 (76.7)	50 (83.3)
Unanswered	0	2 (3.3)
Ethnicity		
Hispanic	11 (18.3)	40 (66.7)
Non-Hispanic	49 (81.7)	20 (33.3)
Age		
18-29	26 (43.3)	26 (43.3)
30-39	18 (30.0)	25 (41.7)
40-49	12 (20.0)	7 (11.7)
<i>50</i> +	4 (6.7)	2 (3.3)
Age - Mean (SD)		
N	60	60
	33.6 (8.9)	32.7 (10.3)

#### **Baseline Surveys**

Baseline surveys were conducted to: 1) To characterize rehabilitation trajectories over time in the areas of function, cognition, psychosocial adjustment, integration into society and mental health disorders over time and 2) To individualize treatment patterns customized to each veterans needs so as to maximize the effect of telerehabilitation. Unlike traditional telemedicine that deals with disease specific monitoring or intervention (diabetes, CHF, dementia etc), our cohort exhibits a very diverse population in terms of disease affliction, complexity and propensity to receive care.

#### **Survey Instruments**

There are nine survey instruments to be completed by study subjects at certain time points while enrolled in the study. They are the Functional Independence Measure and Functional Assessment Measure (FIM/FAM); The Craig Handicap Assessment and Reporting Technique (CHART), The Mayo-Portland Adaptability Inventory (MPAI-4); The Patient Health Questionnaire: (PHQ-2); The Patient Competency Rating Scale (PCRS); Short Form of the PTSD Checklist - Civilian Version (PCL-C); Short Post-Traumatic Stress Disorder Rating Interview (SPRINT); Alcohol Use Disorders Identification Test (AUDIT); and the SF-12 Health Survey. The surveys will all be administered at baseline, 6-months and 12-months. The Patient/Caregiver satisfaction surveys will be conducted after 12 months of continuous enrollment in telerehabilitation. To date, 59 Tampa and 54 Miami subjects have completed the baseline survey instruments. 30 Tampa and 5 Miami subjects have completed the 6 month survey instruments. Some of the key survey instruments utilized are summarized below:

- 1. **Functional Independence Measure**<sup>TM</sup> (**FIM**) and **Functional Assessment Measure** (**FAM**): The (FIM<sup>TM</sup>) <sup>1,2</sup> is a widely accepted functional assessment measure in use in the rehabilitation community. The FIM measures independent performance in motor and cognitive skills in addition to the ADLs pertaining to the self care categories of feeding, grooming, bathing, dressing upper body, dressing lower body and toileting. The FIM is proprietary. We have therefore captured all elements of the FIM in an expanded version of the same which includes elements in Functional Assessment as well. Because disturbances in communication, cognition, and behavior are prominent characteristics after brain injury, additional items considering those issues were added to the FIM, resulting in a functional assessment measure, FIM+FAM.<sup>3</sup> The FIM+FAM has been increasingly adopted as an outcome measure in brain injury rehabilitation. <sup>4,5</sup>
- 2. Craig Handicap Assessment and Reporting Technique (CHART): The CHART provides for assessing assistance levels, time spent (and with whom) and financial resources. The standard deviations in Table 4 indicate variability among veterans in each of the categories listed substantiating our prior finding that our cohort is binary in nature on care needs especially in the areas of cognition and integration into society.
- 3. **Patient Competency Rating Scale (PCRS):** The PCRS provides for a rating of basic competencies in performing everyday chores with responses on a 1-5 scale with 1 denoting the most difficulty in addressing a problem and a score of 5 implying ability to handle the problem with total ease.

Listed below are findings from baseline health status measures for control and study participants from the Functional Independence Measure and Functional Assessment Measure (FIM/FAM), Patient Competency Rating Scale (PCRS), Short Form of the PTSD Checklist - Civilian Version (PCL-C) and The Patient Health Questionnaire (PHQ-2). They concisely describe the cohort followed and are similar in findings to other instruments used to measure outcomes.

# Functional Independence Measure $^{\mathrm{TM}}$ (FIM) and Functional Assessment Measure (FAM)

		/IPA		ЛРА ЛО		AMI		AMI
		LINE				LINE	6 N	STUDY
LABEL	CNTRL N=30	STUDY N=29	CNTRL N=15	STUDY N=15	CNTRL N=27	STUDY N=27	CNTRL N=3	N=2
Feeding	6.6±0.98	6.6±1.07	6.7±0.46	6.7±0.72	6.5±1.37	6.9±0.27	7±0	7±0
Grooming	6.6±0.92	6.3±1.24	6.7±0.49	6.9±0.35	6.4±1.19	6.5±1.4	7±0	7±0
Bathing	6.5±1	6.4±1.33	6.5±0.92	6.9±0.35	6.3±1.36	6.6±0.97	7±0	6.5±0.71
Dressing - Upper Body	6.5±1.23	6.5±1.38	6.7±0.46	6.9±0.35	6.4±1.31	6.7±0.83	7±0	5.5±2.12
Dressing - Lower Body	6.4±1.26	6.3±1.24	6.7±1.05	6.7±0.46	6.2±1.33	6.6±0.97	7±0	5.5±2.12
Toileting	6.8±0.62	6.9±0.31	6.7±0.8	6.9±0.35	6.7±0.55	6.8±0.62	7±0	7±0
Swallowing	6.9±0.25	6.9±0.25	6.9±0.35	6.9±0.26	6.9±0.32	7±0.19	7±0	7±0
Bladder Management	6.7±0.44	6.9±0.31	6.9±0.26	6.7±0.59	6.8±0.51	6.8±0.96	6.7±0.58	5±2.83
Bowel Management	6.6±0.99	6.9±0.31	6.6±1.3	6.7±0.46	6.7±0.61	6.7±0.98	7±0	5±2.83
Bed	6.7±0.63	6.6±0.89	6.7±1.05	6.7±0.46	6.4±1.18	6.7±0.73	5.3±2.89	7±0
Chair	6.6±0.84	6.8±0.41	6.7±0.82	6.9±0.35	6.6±0.63	6.8±0.51	6.7±0.58	7±0
Toiler	6.8±0.62	6.9±0.35	6.7±1.05	6.9±0.35	6.7±0.62	6.9±0.36	6.3±0.58	7±0
Tub or Shower	6.7±0.64	6.7±1.12	6.6±0.83	6.8±0.41	6.2±1.45	6.8±0.4	7±0	6.5±0.71
Car Transfer	6.6±0.75	6.8±0.63	6.6±0.83	6.8±0.41	6.4±1.25	6.8±0.51	7±0	7±0
Wheelchair	6.8±0.75	6.9±0.25	6.9±0.26	6.9±0.26	7±0	6.9±0.42	7±0	6.5±0.71
Walking	6.3±1.05	6.4±1.04	6.6±0.83	6.5±0.83	6.2±1.12	6.4±1.12	7±0	6±0
Stairs	6±1.47	6.3±1.06	6.1±1.62	6.3±0.9	6.1±1.27	6.2±1.37	6.7±0.58	6±0
Ability to Access the Community	6.4±1.05	6.6±0.81	6.6±1.06	6.3±1.05	6.3±1.11	6.7±0.86	7±0	6.5±0.71
Wheelchair	6.8±0.75	7±0.18	6.9±0.35	6.9±0.26	7±0	6.9±0.42	7±0	6.5±0.71
Audio Comprehension	6.2±1.29	6.1±1.16	6±1.13	6.1±1.03	5.7±1.73	5.9±1.73	6±1	6.5±0.71
Visual Comprehension	6.2±1	6.4±1.07	6.3±0.9	6.6±0.83	6.1±1.54	6.5±1.09	6.3±1.15	6.5±0.71
Verbal Expression - What is your ability to express yourself verbally?	6.3±1.09	6.1±1.17	6.4±0.74	6.7±0.62	5.6±1.85	6.1±1.49	7±0	6.5±0.71
Nonverbal Expression	6.4±1.17	6.5±0.86	6.3±1.35	6.7±0.46	6±1.53	6.4±1.39	5.3±2.89	6.5±0.71
Reading	6.1±1.5	5.9±1.57	5.9±1.62	6.4±0.63	5.9±1.63	6±1.54	5±3.46	6.5±0.71
Writing	6.3±1.17	6.3±1.06	6.1±1.36	6.7±0.62	5.7±1.88	5.9±1.76	5.3±2.89	6.5±0.71
Speech Intelligibility	6.3±1.22	6.1±1.31	6.3±1.1	6.7±0.59	6.1±1.41	5.9±1.66	5±3.46	6.5±0.71
Social Interaction	5.6±1.82	5.2±1.98	5.7±1.33	5.3±1.91	4.7±2.37	4.9±2.21	6±1	4.5±2.12
Emotional Status	5.1±1.84	5.2±1.86	5.5±1.46	5.3±1.83	4.6±2.26	4.9±2.14	4.3±2.89	4.5±2.12
Adjustment to Limitations	5.6±1.7	5.4±1.69	5.7±1.49	5.4±1.8	4.9±2.23	4.9±2.13	4.7±3.21	4±2.83
Employability	4.9±2.32	5±2.4	5.8±2.04	5.3±1.98	4.5±2.46	4.8±2.5	6±1	3.5±3.54
Problem Solving	5.8±1.6	5.5±1.85	5.9±1.6	6.2±1.01	5±2.08	5.6±1.78	4.7±3.21	4±2.83
Memory	5.1±1.57	4.5±1.89	4.9±1.64	4.8±1.66	4.4±2.21	4.5±2.05	4±3	3±2.83
Orientation	5.6±1.61	5.3±1.66	5.7±1.71	6.2±1.01	5.1±2.15	5.3±1.86	5±3.46	4±2.83
Attention	5.3±1.62	5±1.87	5.4±1.72	5.1±1.49	4.9±2	5±1.82	4±3	3±2.83
Safety Judgment	5.9±1.51	6±1.63	5.9±1.58	6.3±1.11	5.7±1.81	5.6±1.85	5±3.46	4±2.83

## **Patient Competency Rating Scale (PCRS)**

		TAN	<b>ЛРА</b>		MIAMI				
	BASE	LINE	6 N	ИО	BASE	LINE	6 N	МО	
	CNTRL	STUDY	CNTRL	STUDY	CNTRL	STUDY	CNTRL	STUDY	
VARIABLE	N=30	N=29	N=15	N=15	N=27	N=27	N=3	N=2	
How much of a problem do I have in preparing my own meals?	4.2±0.8	4.3±0.88	4.4±0.83	4.4±0.83	4.1±0.97	4±1.14	5±0	3.5±0.71	
How much of a problem do I have in dressing myself?	4.3±0.94	4.5±0.94	4.5±0.74	4.6±0.63	4±1.16	4.4±0.88	5±0	4±0	
How much of a problem do I have in taking care of my personal hygiene?	4.4±0.83	4.5±0.78	4.5±0.74	4.5±0.64	4.2±0.89	4.4±0.84	4.3±1.15	3±0	
How much of a problem do I have in washing the dishes?	4.1±1.18	4.2±1.1	4.3±0.82	4.2±1.21	4±1.21	4.3±0.88	5±0	3±0	
How much of a problem do I have in doing the laundry?	4.1±1.22	4.3±0.88	4.4±0.91	4.2±1.15	3.9±1.25	4.2±0.8	4.3±1.15	3.5±0.71	
How much of a problem do I have in taking care of my finances?	3.3±1.28	3.8±1.16	3.7±1.35	3.9±0.92	3.6±1.31	3.8±1.09	4.3±1.15	2.5±0.71	
How much of a problem do I have in keeping appointments on time?	3.3±1.07	3.5±1.04	3.9±1.16	3.4±0.83	3.5±1.09	3±1.06	4±1.73	2±0	
How much of a problem do I have in starting conversation in a group?	3.1±1.25	3±1.05	3.4±1.35	2.9±1.03	3.1±1.27	2.9±1.2	3.3±2.08	2.5±0.71	
How much of a problem do I have in staying involved in work activities even when bored or tired?	2.9±1.19	3.2±1.12	2.8±1.32	3.2±1.15	2.7±1.32	2.7±1.27	2.7±1.53	3±0	
How much of a problem do I have in remembering what I had for dinner last night?	3.4±1.24	3.1±1.01	3.2±1.32	3.3±1.03	3.1±1.41	3.1±1.21	3.7±1.15	3±1.41	
How much of a problem do I have in remembering names of people I see often?	3.1±0.94	2.9±1.17	3±0.93	3.1±0.96	2.6±1.21	2.6±1.04	3.3±1.15	2.5±0.71	
How much of a problem do I have in remembering my daily schedule?	3±0.89	3±0.96	3.1±1.03	3.1±0.7	2.9±1.07	2.9±0.99	3.3±1.15	2.5±0.71	
How much of a problem do I have in remembering important things I must do?	3.1±0.86	2.8±0.85	3.1±1.06	3±0.65	2.9±1.01	2.8±0.97	2.3±1.53	2.5±0.71	
How much of a problem would I have driving a car if I had to?	4.3±0.86	4.4±0.73	4.7±0.46	4.5±0.74	4±1.09	4.2±0.89	5±0	4±0	

How much of a problem do I have in getting help when I'm confused?	3.6±0.98	3.7±0.87	3.7±1.11	4±1	3.7±1.14	3.3±1.07	3.3±2.08	3.5±0.71
How much of a problem do I have in adjusting to unexpected changes?	3.1±0.92	3.2±0.99	3.2±1.01	3.5±0.99	3.3±1.17	3.1±1.35	3±1.73	3±0
How much of a problem do I have in handling arguments with people I know well?	2.9±1.09	3.1±1.07	3±1.07	3±1.2	3±1.43	2.7±1.04	3.7±1.15	3±0
How much of a problem do I have in accepting criticism from other people?	2.9±0.99	3.3±1.06	3.1±1.3	3.3±1.05	3±1.16	3.1±1.17	4±1	3±1.41
How much of a problem do I have in controlling crying?	3.8±1.15	4.2±0.91	3.7±1.59	3.7±1.11	3.7±1.3	3.4±1.31	4±1.73	2.5±0.71
How much of a problem do I have in acting appropriately when I'm around friends?	3.9±0.92	4.1±0.78	4.1±0.99	3.7±0.7	3.6±1.24	3.7±0.9	3.3±2.08	3.5±0.71
How much of a problem do I have in showing affection to people?	3±1.09	3±1.1	2.9±1.16	2.9±0.83	2.7±1.11	2.7±0.95	2.7±1.53	2.5±0.71
How much of a problem do I have in participating in group activities?	3.1±1.13	3±1.07	3.2±1.15	2.9±0.88	2.9±1.19	3±0.98	3.3±2.08	2.5±0.71
How much of a problem do I have in recognizing when something I say or do has upset someone else?	3.1±1.06	3.3±0.92	3.1±1.13	3.1±1.13	3±1.16	3±1.09	2.7±1.53	2.5±0.71
How much of a problem do I have in scheduling daily activities?	3.2±0.91	3.5±0.94	3.3±1.1	3.5±0.74	3±1.16	3.1±1.11	3±1.73	2.5±0.71
How much of a problem do I have in understanding new instructions?	3.4±0.82	3.7±0.88	3.3±1.22	3.9±0.88	3.3±1.21	3.3±1.07	2.7±1.53	2.5±0.71
How much of a problem do I have in consistently meeting my daily responsibilities?	3.3±1.04	3.7±0.95	3.5±1.19	3.4±0.74	3.1±1.21	3.1±0.95	2.7±1.53	3±1.41
How much of a problem do I have in controlling my temper when something upsets me?	2.7±1.01	2.8±0.97	2.8±1.01	2.5±0.92	2.6±1.08	2.6±0.93	2±0	1.5±0.71
How much of a problem do I have in keeping from being depressed?	2.7±1.13	3.3±1.12	2.9±1.03	2.9±0.96	2.4±1.01	2.5±1.09	2.3±1.53	1.5±0.71
How much of a problem do I have in keeping my emotions from affecting my ability to go about the day's activities?	3±1.2	3.4±1.07	3.2±0.86	3.3±1.03	2.9±1.23	2.9±1.13	2.3±1.53	1.5±0.71

How much of a problem do									
I have in controlling my	4±0.96	4.3±0.94	4.1±0.92	4.3±0.96	4.1±0.91	4±0.94	3.3±2.08	4±0	
laughter?									

## Short Form of the PTSD Checklist - Civilian Version (PCL-C)

		TAN	<b>ЛРА</b>		MIAMI			
	BASE	LINE	6 N	ИО	BASE	LINE	6 N	ИО
	CNTRL	STUDY	CNTRL	STUDY	CNTRL	STUDY	CNTRL	STUDY
VARIABLE	N=30	N=29	N=15	N=15	N=27	N=27	N=3	N=2
Repeated, disturbing memories, thoughts, or images of a stressful experience from the past?	2.5±1.12	3±1.19	2.6±1.06	3.2±1.08	2.1±1.25	2.3±1.03	3±1.73	2.5±0.71
Repeated, disturbing dreams of a stressful experience from the past?	2.8±1.18	3.1±1.25	3.1±1.22	3.1±1.03	2.3±1.32	2.5±1.22	3±1.73	2.5±0.71
Suddenly acting or feeling as if a stressful experience were happening again (as if you were reliving it)?	3.1±1.16	3.5±1.22	2.8±1.21	3.7±1.03	2.7±1.36	2.8±1.3	3±2	3±0
Feeling very upset when something reminded you of a stressful experience from the past?	2.6±1.21	2.9±1.06	2.8±1.08	3.1±0.96	2±1.24	2.5±1.19	3±2	2±0
Having physical reactions (e.g., heart pounding, trouble breathing, or sweating) when something reminded you of a stressful experience from the past?	2.8±1.2	3.1±1.09	2.9±1.28	3.1±1.13	2.4±1.37	2.6±1.25	2.7±2.08	2.5±0.71
Avoid thinking about or talking about a stressful experience from the past or avoid having feelings related to it?	2.7±1.28	2.8±1.37	3.5±1.3	3±1.2	1.9±1.17	2.2±1.12	3.3±2.08	2.5±0.71
Avoid activities or situations because they remind you of a stressful experience from the past?	2.7±1.42	3±1.41	3.3±1.49	2.9±1.1	2±1.14	2.5±1.19	3±2	2.5±0.71
Trouble remembering important parts of a stressful experience from the past?	3.4±1.24	3.2±1.27	3±1.07	3.4±1.3	3.6±1.22	3±1.43	3.7±2.31	2.5±0.71
Loss of interest in things that you used to enjoy?	2.4±1.4	2.6±1.25	2.7±1.35	2.7±0.72	2±1.04	1.8±1	2.3±2.31	1.5±0.71
Feeling distant or cut off from other people?	2.5±1.38	2.7±1.26	2.5±1.25	3±1.07	1.9±1.14	2.2±1.3	2.3±2.31	2.5±0.71
Feeling emotionally numb or being unable to have loving feelings for those	2.8±1.33	2.8±1.41	2.5±1.46	3±0.85	2±1.13	2.2±1.27	2.3±1.53	2±0

close to you?								
Feeling as if your future will somehow be cut short?	3.2±1.24	3.5±1.53	3.1±1.55	3.7±1.16	2.8±1.63	2.5±1.34	2.7±2.08	3±1.41
Trouble falling or staying asleep?	1.8±1.11	2.1±1.18	1.9±1.22	2.4±1.06	1.9±1.1	1.6±0.7	2±1.73	2.5±0.71
Feeling irritable or having angry outbursts?	2.4±1.15	2.6±1.25	2.6±0.99	2.7±0.82	2.3±1.27	2.1±1.05	2.3±1.53	2.5±2.12
Having difficulty concentrating?	2.3±1.17	2.5±1.14	2.3±1.28	2.5±0.92	1.9±1.17	1.9±0.97	2.3±1.53	2.5±0.71
Being super alert or watchful on guard?	2±1.24	2.3±1.24	2.1±1.16	2.3±1.11	1.7±1.04	1.9±1.03	2.3±2.31	2±1.41
Feeling jumpy or easily startled?	2.3±1.17	2.8±1.29	2.5±1.19	2.7±1.18	2±1.13	2.1±1.17	2±1.73	2.5±0.71

### The Patient Health Questionnaire: (PHQ-2)

		TAN	IPA		MIAMI				
	BASE	BASELINE		6 MO		BASELINE		ИО	
	CNTRL			STUDY	CNTRL	STUDY	CNTRL	STUDY	
VARIABLE	N=30	N=29	N=15	N=15	N=27	N=27	N=3	N=2	
Little interest or pleasure in doing things.	2.5±1.09	2.6±1.07	2.7±0.88	2.7±0.8	1.9±0.92	1.9±1.04	2±1.73	2.5±0.71	
Feeling down, depressed, or hopeless.	2.6±1.05	2.9±1.01	2.7±0.88	2.7±0.8	2.1±0.87	2±1.02	2.3±1.53	2±1.41	

## **Conclusion**

### **Problem Areas**

At this time we do not anticipate any problems in recruitment and retention.

## A description of work to be performed during the next reporting period.

We have completed enrollment at Tampa and Miami. We expect to begin preliminary data analysis later this year.